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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/139,386	08/25/1998	JOSEPH ALBERT MONFORTE	24736-2060	5243

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HELLER EHRMAN WHITE & MCAULIFFE LLP
4350 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122-1246

EXAMINER	
TUNG, JOYCE	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/139,386	MONFORTE ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/5/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Following the entry of the amendment filed 12/5/2003, the claims 1-21 are pending.

1. Claims 1-15 and 18-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Hiatt et al. (5,763,594, issued 6/1998).

Hiatt et al. disclose a nucleic acid primer having a 5' end and a 3' end comprising:

(a) a first region containing the 5' end of the primer and an immobilization attachment site (See column 17, lines 51-67 to column 18, lines 1-6).

(b) a second region containing the 3' end of the primer including a free 3' hydroxyl and a selectively chemically cleavable site (See column 17, lines 51-67 and column 18, lines 1-20) wherein the 3' end is capable of being extended by an enzyme to generate an extension segment (See column 4, lines 5-11 and column 4, lines 55-58).

The selectively chemically cleavable site comprises a modified base or a modified sugar or a chemically cleavable group incorporated into the phosphate backbone including 3'-phophorothioate, 3' phosphoramidate (See column 4, lines 61-67).

The enzyme is a DNA polymerase or ligase (See column 19, lines 38-55).

The intervening space arm is six or more atoms in length (See column 17, lines 54-63).

The solid support is selected from the group consisting of glass, silicon and as listed in claim 14 (See column 4, lines 49-54).

The solid support comprises a functionality selected from the group consisting of avidin and streptavidin (See column 19, lines 7-11).

Immobilization attachment site is biotin (See column 19, lines 7-11) or a single stranded nucleic acid (See column 17, lines 51-67).

The teachings of Hiatt et al. do not explicitly disclose that a second region contains a selectively chemical cleavage. However, the 3' end of the nucleic acid of Hiatt et al. is cleaved

with 1M piperidine (See column 17, lines 53-67). It is selectively chemical cleavage. Thus, the teachings of Hiatt et al. anticipate the limitations of claims.

The response argues that Hiatt et al. do not disclose a nucleic acid primer having a second region at the 3' portion that includes a free 3' hydroxyl and a selectively chemically cleavable site. However, it appears that the claim language does not clearly indicate that there is a selectively chemically cleavable site at the 3' portion. The claim language states "a second region containing the 3' end of the primer including a free 3' hydroxyl and a selectively chemically cleavable site". So it is unclear whether or not the selectively chemically cleavable site is at the very 3' end of the primer.

The response further argues that Hiatt et al. disclose that the blocking group is removed, and then the oligonucleotide would have a free 3' hydroxyl that is available for use as a primer. The claim language does not require that the 3' end of the primer has a blocking group. Thus, the limitations are not presented in the claims.

In fact, Hiatt et al. do disclose the oligonucleotide having a free 3' hydroxyl and a selectively chemically cleavable at 3' end of the oligonucleotide (See column 17, lines 51-67 and column 18, lines 1-20). Therefore, the teachings of Hiatt et al. still anticipate the limitations of claims. The rejection is maintained.

2. Claims 21 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Hiatt et al. (5,763,594, issued 6/1998) as applied to claims 1-15 and 18-20 above, and further in view of Koster (5,547,835, issued 8/20/1996).

The teachings of Hiatt et al. are set forth in section 1 above. Hiatt et al. do not disclose using the single stranded nucleic acid complementary to an intermediary oligonucleotide bound to the solid support.

Koster discloses a new method to sequence DNA. The nucleic acid oligonucleotide primer is involved in the method. The primer carries a linking functionality, L, at 5' end which can include a spacer arm and interact with a suitable functionality, L', on a solid support (See column 11, lines 52-63). The linkage has the purpose to capture the nested Sanger DNA or RNA fragment (See column 11, lines 66-67 to column 12, lines 1-30). The nested Sanger DNA/RNA fragments are captured via Watson-crick base pairing to a solid support-bound oligonucleotide complementary to the nucleic acid primer (See column 12, lines 51-56).

One of the ordinary skill in the art would have been motivated to modify the immobilization of the oligonucleotide of Hiatt et al. by applying the hybridization of the oligonucleotide on the solid support via nucleic acid linker as taught by Koster. Koster discloses that the solid support bound base sequence renders the base sequence less susceptible to enzymatic degradation and hence increases overall stability of the solid support-bound capture base sequence (See column 12, lines 57-65). It would have been prima facie obvious to have the single stranded nucleic acid which is complementary to an intermediary oligonucleotide bound to the solid support.

The response argues that Hiatt et al. do not anticipate the limitations of claims and Koster fails to cure the deficiencies in the teachings of Hiatt et al.. As set forth in section 1 above the teachings of Hiatt et al. do anticipate the limitations of the claims. The teachings of Koster and the motivation of applying the teachings of Koster to render the limitations of claim 21 which are obvious are discussed abvove. The rejection is maintained.

3. Claims 16-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hiatt et al. (5,763,594, issued 6/1998) as applied to claims 1-15 and 18-20 above, and further in view of Edwards et al. (5,306,619, issued 4/26/1994).

The teachings of Hiatt et al. are set forth in section 1 above. Hiatt et al. do not disclose that the solid support comprises an antibody comprising anti-digoxigenin.

Edwards et al. disclose a DNA:protein binding assay in which the target oligonucleotide is attached to a solid support by using an anti-digoxigenin which is attached on the solid support (See column 4, lines 51-56).

One of ordinary skill in the art would have been motivated to modify the solid support of Hiatt by using an anti-digoxigenin to attach the oligonucleotide to a solid support. Edward et al. states that the method is for identification of molecules that specifically bind to defined nucleic acid sequence (See column 1, lines 10-12 and column 2, lines 49-55). It would have been prima facie obvious to apply anti-digoxigenin to solid support to immobilize oligonucleotide.

The response argues that Hiatt et al. do not anticipate the limitations of claims and the combination of the teachings Hiatt et al. and Edwards et al. do not result in the subject matter of the claims 16-17. As set forth in section 1 above, the teachings of Hiatt et al. do anticipate the limitations of the claims. As discussed above, the combination of the teachings of Hiatt et al. and Edwards et al. does render the prima facie obvious of the limitations of claims 16-17. The rejection is maintained.

Summary

4. No claims are allowable.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung
S. T
February 25, 2004

ETHAN WHISENANT
PRIMARY EXAMINER